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Sinpei Nakata

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MATTINGLY & MALUR, P.C.
1800 DIAGONAL ROAD
SUITE 370
ALEXANDRIA, VA 22314

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte SINPEL NAKATA, TAKEHIKO YOTSUGI,
and HIROAKI ISHIZAWA

Appeal 2009-009058
Application 09/936,918
Technology Center 1700

Decided: November 30, 2009

Before BRADLEY R. GARRIS, CHUNG K. PAK, and PETER F. KRATZ,
Administrative Patent Judges.

KRATZ, *Administrative Patent Judge.*

DECISION ON APPEAL

This is a decision on an appeal under 35 U.S.C. § 134 from the Examiner's final rejection of claims 1-5, 7-20, and 22-24. We have jurisdiction pursuant to 35 U.S.C. § 6. Oral arguments were presented on November 19, 2009.

Appellants' claimed invention is directed to an automatic analysis and information management method using a service center in communication with a plurality of automatic analysis apparatuses located at a plurality of facilities. The service center stores and classifies analysis parameters for reagents used in the plurality of automatic analysis apparatuses of the plurality of facilities in a database. The service center communicates, upon a request received from one of such automatic analyzing apparatuses, a list of reagents available at said apparatus. Upon selection of a reagent from the list by a user of such particular apparatus, the service center further communicates analysis parameters for a particular test to be carried out by that analysis apparatus using the operator selected reagent. Appellants' claimed method includes the steps of adding the selected reagent to a control sample in the one automatic analysis apparatus and analysis of the control sample by the one automatic analysis apparatus. In conducting the method, the service center calculates a statistical standard value for analysis results based on results of analyses on control samples that employ the same reagent, as compiled from all automatic analysis apparatuses and facilities administered by the service center. Also, the service center calculates a statistical deviation of the analysis result from the standard value and determines whether the analysis parameters used in the analysis are correct.

Claim 1, the sole independent claim on appeal, is illustrative and reproduced below:

1. An analysis information management method using a service center connected through communication lines to a plurality of automatic analyzing apparatuses used in a plurality of facilities, said service center having a database for storing analysis parameters related to a plurality of reagents for use in the plurality of automatic analyzing apparatuses used in the plurality of facilities, the method comprising the steps of:

creating, by said service center responsive to a request from one of said automatic analyzing apparatuses, a list of reagents available in said one automatic analyzing apparatus from information on reagents stored in said database, and supplying said one automatic analyzing apparatus with the list through a communication line;

transferring, by said service center responsive to a selection of an associated reagent from said list, made by a user of said one automatic analyzing apparatus, analysis parameters, according to which a test is to be carried out on a testing item to be analyzed using the selected reagent, to said one automatic analyzing apparatus through said communication line;

wherein said service center classifies and stores information, including results of calibrations measured by said automatic analyzing apparatuses, results of analyses on control samples, reagents used in analyses, and analysis parameters, for tests carried out in each facility or for each automatic analyzing apparatus, wherein the results of analyses on said control samples are derived from analyses of said control samples using the same reagents in all automatic analyzing apparatuses in all facilities administered by said service center;

calculating, by said service center based on the stored information on the results of analyses for each facility or for each automatic analyzing apparatus, a statistical standard value defined for said results of analyses on said control samples using the same reagents in all automatic analyzing apparatuses in all facilities administered by said service center;

adding said selected reagent to a control sample in said one automatic analyzing apparatus;

analyzing a control sample by said one automatic analyzing apparatus;

calculating, by said service center, a statistical deviation for the result of analysis from said standard value for evaluation; and

determining, based on the calculated statistical deviation, whether the analysis parameters used in the analysis are correct.

The Examiner relies on the following prior art references as evidence in rejecting the appealed claims:

Carbonari	5,730,938	Mar. 24, 1998
Fritchie	6,022,746	Feb. 8, 2000

The only outstanding rejection for review on this appeal is a new ground of rejection set forth by the Examiner in the Answer (*Ans.* 2-4). The rejection is as follows:

Claims 1-3, 6, and 8-12 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Fritchie in view of Carbonari.¹

The principal issue before us is:

Have Appellants shown that the Examiner erred by failing to set forth a prima facie case of obviousness with respect to claim 1, the sole independent claim on appeal?

We answer this question in the affirmative. Consequently, we reverse the sole ground of rejection before us for substantially the reasons set forth by Appellants in the non-rebutted Reply Brief presented by Appellants in reply to the aforementioned new ground of rejection (*Reply Br.* 7-12, 19).

Fritchie is directed to a method of allocating system resources to multiple testing instruments. In particular, Fritchie teaches “a method of allocating resources or supplies, such as reagents, disposables and the like,

¹ See the Office Communication of February 23, 2009 for a corrected statement of the new ground of rejection.

in a medical diagnostic system” that involves resource or supply allocation among several connected machines or instruments (col. 1, ll. 6-9 and ll. 18-40). In disclosed and illustrated embodiments, Fritchie discloses a system (10) including four instruments (12A-D) connected to a common supply of samples and including a computer or controller (14), among which instruments the tests to be performed are allocated (col. 2, ll. 3- 62). Fritchie further explains the allocation method among the testing instruments throughout the remainder of the Patent Specification.

Carbonari discloses an automatic chemical analyzer comprising a carousel including a plurality of removable reagent containers, a turntable for receiving multiple sample fluid holders, and a rotatable cuvette assembly including an annular array of reaction and test cuvettes (Abst.). A colorimetry photometric test is run on reacted fluids in the cuvettes. (*Id.*) Cleaning of the cuvettes follows completion of a photometric test cycle in all of the cuvettes. (*Id.*) A programmable computer is used for interfacing with an operator for data input and for controlling the tests (col. 3, l. 38 –col. 4, l. 48).

The Examiner points to Carbonari’s disclosure and assertion that “[a] built in quality control system monitors the tests for statistical deviations. All of these and other functions and parameters are within the skill of those of ordinary skill to implement” (col. 4, ll. 14-17).

The Examiner maintains that:

[i]t is known and desirable to monitor the statistical deviation of the data to determine the certainty and confidence of the results. The Office has read this on the claimed " ... calculating, ... a statistical standard value ... calculating ... a statistical deviation ... determining, based on the calculated

statistical deviation, whether the analysis parameter used in the analysis are correct."

It would have been within the skill of the art to modify Fritchie et al. in view of Carbonari et al. and include a quality control system that tests for statistical deviations to determine the certainty and confidence of the results.

Ans. 4.

Even if we could agree with the Examiner that it would have been obvious to one of ordinary skill in the art at the time of the invention to modify Fritchie's allocation method to include a quality control system based on the teachings of Carbonari as generally proposed by the Examiner, the Examiner has not satisfactorily explained how the proposed modification would have resulted in a method having all of the required limitations of rejected independent claim 1 (Ans. 5).

For example, the Examiner basically contends that system 10 of Fritchie teaches or suggests a method that includes the use of a service center as claimed, including a service center connected to a plurality of automatic analysis apparatuses used in a plurality of facilities, as required by all of the appealed claims (Ans. 5). The Examiner refers to system (10), instruments 12A-12D, and the disclosure at column 6, lines six through sixteen of Fritchie (*id.*). However, Fritchie's system (10) is not separate from instruments 12A-12D but includes such instruments, which instruments are connected to a common supply of samples and a controller (14). The Examiner does not persuasively address what portions of the system (10) of Fritchie relate to each of the here claimed method steps and/or how they can be modified to meet the here claimed method steps.

In particular, appealed claim 1 is not drawn to a method of allocating resources to instruments connected to a common supply of samples to be analyzed, as in Fritchie, but rather to an analysis and information management method wherein a service center is connected to a plurality of automatic analysis apparatuses in a plurality of facilities via communication lines. The claim 1 method includes the steps of the service center receiving a request from one of the automatic analyses apparatuses, the service center generating a list of available reagents at the one automatic analysis apparatus from which the request was received and supplying that particular apparatus with the list via a communication line. After a user of the one automatic analysis apparatus makes a reagent selection from the communicated list, in the claimed method the aforementioned steps are followed by the service center transferring analysis parameters to the said one automatic analysis apparatus according to the test to be carried out at the one analysis apparatus based on the user selected reagent.

It is well settled that the burden of establishing a prima facie case of non-patentability resides with the Examiner. *See In re Piasecki*, 745 F.2d 1468, 1472 (Fed. Cir. 1984). Here, the Examiner's reliance on and references to Fritchie's method of allocating testing workload among several analysis instruments has not been accompanied by an adequate explanation as to how Fritchie, taken with Carbonari, teaches or would have suggested all of the aforementioned claim 1 method steps so as to fulfill the Examiner's burden of presenting a prima facie case of obviousness, as urged by Appellants (Reply Br. 7-12).

In this regard, the Examiner has not presented a sustainable basis for the obviousness rejection because the Examiner has not furnished sufficient

fact findings respecting the relied upon prior art disclosures coupled with a detailed correlation thereof with all of the claim requirements. In this regard, “rejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness” being asserted. *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006) (quoted with approval in *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 418 (2007)). After all, rejections based on § 103(a) must rest on a factual basis with these facts being interpreted without hindsight reconstruction of the invention from the prior art. *See In re Warner*, 379 F.2d 1011, 1017 (CCPA 1967).

On this record, we reverse the Examiner’s obviousness rejection of the appealed claims.

ORDER

The Examiner’s decision to reject claims 1-3, 6, and 8-12 under 35 U.S.C. § 103(a) as being unpatentable over Fritchie in view of Carbonari is reversed.

REVERSED

sld

MATTINGLY & MALUR, P.C.
1800 DIAGONAL ROAD
SUITE 370
ALEXANDRIA, VA 22314